

DECLARATION OF CONFORMITY

Manufacturer's Name: Th. Kazantzidis S.A. - MEDIPAC

Manufacturer Address: Industrial Area Kilkis, 611 00 Kilkis Greece

Name of medical device: Surgical Suture PROPYLEN

GMDN No: 13909

Categorization: III - under rule 8 of Annex IX of Directive 93/42/EEC

The undersigned, declares that the non absorbable monofilament suture Polypropylene under the trade name PROPYLEN, is according to the requirements of Directive 93/42/EEC and DY8d /1348/2004 of the Greek Ministry for Health and Social solidarity regarding distribution of medical devices.

We, at Th. Kazantzidis S.A. - MEDIPAC, also declare that the shelf life of PROPYLEN suture is **4 years** and it should be stored **below 25°C** and away from direct heat and moisture.

This statement is supported by:

The EC declaration of conformity of quality system adopted by the EKAPTY, notified body, with identification number 0653. This statement is issued by the certificate (Number of Certificate 301041049, 301041049DE7 Certificates expiration date: 24/05/2024) and supersedes any previous statement has been issued for this product.

Date: 20/07/2021

Kazantzidis Themistoklis

Managing Director

NUMBER AL SUPPLIES

NUMBER AL AREA 61100 KILKIS, GREECE, EO. BOX: 1

2: +30 23410 71991. F.: +30 23410 71979

VAT: EL094148227 - GEMI: 014486935060